

**Amendments to the Drawings:**

The drawing Figures 4 and 5 have been amended. Appended to this amendment is an annotated copy of the previous drawing sheet, which has been marked to show changes presented in the replacement sheet of the drawing.

The specific changes which have been made to Figures 4 and 5 are removal of the label “prior art.”

### **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 34 is currently being amended.

This amendment changes claims and deletes the text of claim 31, which was previously canceled in the above captioned application. Claim 34 has been amended to add a limitation found in several of the other independent claims (e.g., see Claim 1). A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1-30 and 32-48 are now pending in this application.

### **Drawings**

FIG. 4 and FIG. 5 have been amended to remove the label “prior art.” Support for this amendment can be found within the originally filed application, at least within the description of the drawings, which recites that “FIG. 4 is a perspective view of a processing/expressor chamber mated to a hub according to an embodiment of the present invention.” and “FIG. 5 is a perspective view of an assembled plurality of processing/expressor chambers according to another embodiment of the present invention.”

The drawings had been objected to in a previous action in the above-captioned application mailed on September 13, 2005. In that action, the Examiner objected to the drawings because “only that which is old is illustrated.” In particular, the Examiner considered that “Fig. 4 is essentially identical to Fig. 10 of US 2002/0107131 and Fig. 5 is essentially identical to Fig. 9 of US 2002/0107131.”

The label “prior art” is inappropriate for each of FIG. 4 and FIG. 5, because the figures illustrate embodiments of the present invention. Although FIG. 4 and FIG. 5 may appear to be

essentially identical to FIG. 10 and FIG. 9 of US 2002/0107131, as observed by the Examiner, this is not the case. Each of FIG. 4 and FIG. 5 shows the processing/expressor chambers; however, the inventive aspects, such as the integrally formed first mating portion are not readily observable. Because FIG. 4 and FIG. 5 illustrate the processing/expressor chambers of the present invention they do not illustrate only that which is old.

**Failure to Comply with 37 C.F.R. §1.121(c)**

The text of cancelled Claim 31 has been removed in the amended claim listing.

**Rejections Under 35 U.S.C. §102(b)**

Claims 1-30 and 32-48 stand rejected under 35 U.S.C. §102(b) in view of various references, which will be discussed in turn.

**A. U.S. Patent No. 3,675,846 to Drucker**

Claims 1-6, 11, 13-18, 24-29, and 34 stand rejected under 35 U.S.C. §102(b) in view of U.S. Patent No. 3,675,846 to Drucker (“Drucker”). Applicants disagree with the Examiner’s rejection.

Briefly, the present invention includes a bag for use in centrifugal processing. The bag includes a substantially circular enclosure having a central opening. As recited in independent Claim 1, “the central opening includes an integrally formed first mating portion for mating with a corresponding second mating portion of the hub.” For example, the integrally formed first mating portion can include a raised area, such as a half-circle cross-section, acting as a built in O-ring. A correspondingly arranged hub has a recess positioned to receive the raised portion.

Turning attention briefly to the prior art, Drucker describes a continuous-flow centrifuge head including a plastic bag that rotates with the chamber serving as a liner for the chamber. (Col. 2, lines 56-57). In particular, “the plastic bag is suspended around a neck 55a on the central bracket 55.” The bag may be supported by cords around its neck and around the neck 55a of the

bracket, or by an O-ring in the upper annular groove 55b. (Col. 2, lines 52-60). Thus, the neck of the bag follows the contours of the central bracket 55, around its neck 55a and into the upper annular groove 55b.

The Examiner is of the opinion that Drucker's bag includes a central opening, which includes an integrally formed first mating portion, referring to items "55a, 55b". Applicants respectfully disagree with the Examiner's suggestion that items 55a, 55b represent an "integrally formed first mating portion" of a bag as recited in Applicants' claim. Drucker describes a neck 55a on a central bracket 55 (Col. 2, lines 52-53) and an annular groove 55b (Col. 2, lines 59-60). Clearly, the neck 55a is "on the central bracket 55" and not part of the bag. Similarly, the annular groove 55b is also a feature of the bracket 55. (As shown in FIG. 3, lines extend from reference number 55b through the bag and to the surface of the annular groove of the central bracket 55.)

Thus, it would be impossible for Drucker's neck 55a to be "integrally formed" to the bag as recited in Applicants' claim, because the neck and the bag are different structures. Although the bag may follow the contour of the neck 55a and annular groove 55b of the bracket 55, there is nothing to suggest that the bag is integrally formed in this or any particular fashion. Further, Drucker relies on a separate structure to support the bag on the central bracket 55. Namely, Drucker describes using a cord, or an O-ring. Nowhere does Drucker disclose, teach, or suggest that the bag has any integrally formed first mating portion.

Thus, Applicants cannot agree that all of the recited elements in independent Claim 1 are found in Drucker, at least because Drucker fails to disclose, teach or suggest a bag having a central opening that includes "an integrally formed first mating portion." Applicants respectfully request withdrawal of the rejection of independent Claim 1.

Independent Claims 13, 24 and 34 as amended herein recite similar limitations to independent Claim 1 and are not anticipated by Drucker for at least the same reason as Claim 1.

Dependent Claims 2-6 and 11 depend directly or indirectly from independent Claim 1, dependent Claims 14-18 depend directly or indirectly from independent Claim 13, and Claims 25-29 depends indirectly from independent Claim 24. Accordingly, each of dependent claims 2-6, 11, 14-18, and 25-29 contain all the elements of the respective independent claim and are not anticipated by Drucker for at least the same reasons. Applicants respectfully request withdrawal of the rejection of Claims 2-6, 11, 13-18, and 24-29.

**B. U.S. Patent No. 4,610,369 to Mercier**

Claims 1-23 stand rejected under 35 U.S.C. §102(b) in view of U.S. Patent No. 4,610,369 to Mercier (“Mercier”). Applicants disagree with the Examiner’s rejection.

Briefly, Mercier describes a pressure vessel including a rigid container having a deformable partition therein and a plurality of closure elements normally extending radially outward. (Abstract). The pressure vessel includes a pair of ports for charging and discharging the vessel with two fluids. A chamber “C” is defined between the rigid container and the deformable partition for storing a fluid. The fluid can be ejected from the chamber by forcing air into the deformable partition. Air enters the deformable partition through the bellows. The bellows includes apertures formed in its convoluted surface through which air is forced. The convoluted surface provides more surface area to accommodate apertures having greater surface area.

The Examiner suggests that Mercier’s flexible closure element 33 (bellows) is a bag comprising a substantially circular enclosure. Applicants respectfully disagree. At column 3, lines 66-68, Mercier describes the flexible closure element 33 as a bellows of flexible material less stretchable than the material of the bladder 13. The bellows is describes at column 4, lines 3-4 as having a plurality of convolutions. (See FIGs. 1, 2, 3, and 6).

First, Mercier’s bellows is not a substantially circular enclosure as recited in Applicants’ independent Claim 1. Although either end of the bellows may have a circular profile, the ends alone do not make the enclosure. The enclosure of Mercier includes both end portions and side portions, which are described and shown as having a plurality of convolutions yielding the

bellows shape. Granted, Applicants' assembly 500 of processor bags may be perceived as having a bellows shape, Applicants' claimed invention is directed one or more bags, with each bag having a substantially circular enclosure as shown in Applicants' FIG. 2A and 2B, and FIG. 4. Thus, Applicants enclosure refers to one of the processor bags of the assembly 500 of processor bags.

Second, the flange described by Mercier is different from the integral seal claimed by Applicants. Mercier describes at column 4, lines 12-15 that "each of the walls 35, 37' has an outwardly extending flange 39, 40, which snugly encompasses the outer surface 38 of the guide tube." Mercier further describes the "outer surfaces of flanges 39 and 40 have an annular groove 41, into which an O-ring 42 is positioned to securely retain the associated flange in position. The O-ring forces a portion of the flange material into an associated annular groove 42'. This is different from Applicants' claimed centrifuge bag having an integrally formed first mating portion. Mercier relies on a separate O-ring that forces the flanges 39, 40 into an associated annular groove 42'. Mercier relies on the O-ring, separate from the bellows 33, to alter the natural shape of the extending flange 39, 40, forcing it into the annular groove 42'.

Thus, Applicants cannot agree that all of the recited elements in independent Claim 1 are found in Mercier, at least because Mercier fails to disclose, teach or suggest a bag having "a substantially circular enclosure." Applicants respectfully request withdrawal of the rejection of independent Claim 1.

Independent Claims 13 recites similar limitations to independent Claim 1 and is not anticipated by Mercier for at least the same reason as Claim 1.

Dependent Claims 2-12 depend directly or indirectly from independent Claim 1, and dependent Claims 14-23 depend directly or indirectly from independent Claim 13. Accordingly, each of dependent claims 2-12 and 14-23 contains all the elements of the respective independent claim and are not anticipated by Mercier for at least the same reasons. Applicants respectfully request withdrawal of the rejection of Claims 2-23.

**C. U.S. Patent Application Publication No. 2002/0107131 to Jorgensen et al.**

Claims 1-29, and 34 stand rejected under 35 U.S.C. §102(b) in view of U.S. Patent Application Publication No. 2002/0107131 to Jorgensen et al. (“Jorgensen et al.”). Applicants respectfully disagree.

At least one of the Applicants in the present case is also a joint inventor of the Jorgensen et al. application. Applicants note that the present invention represents an improvement over the Jorgensen et al. at least in that Applicants present invention includes an integrally formed first mating portion. Contrary to the Examiner’s assertion, Jorgensen et al. fails to disclose, teach or suggest that the bag includes an integrally formed first mating portion, as recited in Applicants’ claims.

Prior art centrifuge processing bags, such as those described in U.S. Patent Application Publication No. 2002/0107131 to Jorgensen et al. do not include an integrally formed first mating portion. As a result, the prior art bags are susceptible to slippage at the joint between the bag and the hub. The centrifugal forces experienced by the fluid-filled bag pull the prior art bags away from the hub. Without an integrally formed first mating portion, the prior art bags are prone to slippage at the joint to the hub. Beneficially, Applicants’ integrally formed first mating portion of the bag together with the corresponding second mating portion provide a more reliable technique for joining a centrifuge processing bag to a central hub.

The Examiner refers to Jorgensen’s description at paragraph 0043 and features identified by reference numbers 20, 60, and 104. Applicants note that the features identified by reference numbers 20, 60, and 104 refer to features of the hub and not the bag. Jorgensen et al. describes at paragraph 0043 that “the bags 10, 50 have an axial aperture 11, 51 where the central hub is joined.” Although the hubs and weld rings may be part of a bag assembly, they are not part of the bag, because Jorgensen et al. describes that they are joined to the bag.

The Examiner repeated points to FIGs. 2, 3, 5, and 6 of Jorgensen et al. for support that the first mating portion comprises an integrally molded radial barrier; one or more raised areas

formed adjacent to the opening; and a circumferential ring of raised material. Nowhere does Jacobson et al. describe any such features relating to the first mating portion.

It is inconceivable how FIGs. 2 and 6 lend any support to the integrally formed first mating portion (of the bag) as they illustrate the hubs 20, 60. As previously noted, the hubs are not part of the bags 10, 50. FIG. 3 shows an expressor bag/central hub assembly 31, 32 in cross section. No detail is apparent to even suggest that the bag includes any integrally formed first mating portion, as recited in Applicants' claims. Similarly, FIG. 5 shows a processing bag 50, having an axial aperture 51. Jacobson et al. fails to described further detail of FIG. 5 anywhere within the specification. Thus, Jacobson et al. fails to disclose, teach, or suggest a bag having an integrally formed first mating portion.

To the extent the Examiner relies on the annular lines, or circles of FIG. 5 shown about the axial aperture 51, Applicants note there is no supporting description that these lines in any way relate to an integrally formed first mating portion. These lines might be inked markings on the bag, or depressions formed after the bag is combined with the hub and the weld ring. Applicants respectfully request withdrawal of the rejection of independent Claim 1.

Independent Claims 13, 24, 34 recites similar limitations to independent Claim 1 and are not anticipated by Jorgensen et al. for at least the same reason as Claim 1.

Dependent Claims 2-12 depend directly or indirectly from independent Claim 1, and dependent Claims 14-23 depend directly or indirectly from independent Claim 13. Accordingly, each of dependent claims 2-12 and 14-23 contain all the elements of the respective independent claim and are not anticipated by Mercier for at least the same reasons. Applicants respectfully request withdrawal of the rejection of Claims 2-23 and 34.



**Rejections Under 35 U.S.C. §103(a)**

Claims 30, 32-33, and 35-38 stand rejected under 35 U.S.C. §103(a) in view of various references, which will be discussed in turn. Applicants hereby traverse the rejections and respectfully request withdrawal of this rejection in consideration for the following arguments.

**A. U.S. Patent Application Publication No. 2002/0107131 to Jorgensen et al.**

Claims 35-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131). The Examiner asserts that Jorgensen teaches by implication, a process of welding a bag to a weld ring through solvents or heat. Assuming *arguendo* that it does, Jorgensen still does not teach or suggest a bag having an integrally formed first mating portion as recited in amended Claim 34, from which dependent Claims 35-38 depend directly or indirectly. Since the integrally formed first mating portion is part of the bag being welded to the second mating portion on the hub, Jorgensen can't be read as disclosing the claimed method of sealing a centrifuge bag to the hub. Accordingly, Jorgensen itself cannot be used to establish *prima facie* obviousness against the claimed invention. Applicants respectfully request withdrawal of the rejection of Claims 35-38.

**B. Jorgensen et al. in view of U.S. Patent No. 3,982,691 to Schlutz**

Claims 30, 32, and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131) in view of U.S. Patent No. 3,982,691 to Schlutz ("Schlutz").

The Examiner characterizes Schlutz as teaching the use of adhesives to join the centrifuge bag components, but it does not offer Schlutz with respect to any particular distinctive elements of the centrifuge bag components itself. Thus, Schlutz does not cure the deficiencies of Jorgensen et al., which does not itself disclose Applicants' claimed centrifuge bag, i.e., when taken in combination, the two references do not disclose, teach, or suggest at least a centrifuge bag having an integrally formed first mating feature, as recited in Applicants' claimed invention. Since Jorgensen et al. and Schlutz in combination do not disclose each and every element of the claimed invention, these two references, alone or in combination cannot be used to establish

*prima facie* obviousness against Applicants' claimed invention. Applicants respectfully request withdrawal of the rejection of Claims 30, 32, and 33.

**Conclusion**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-3431. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-3431. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-3431.

Respectfully submitted,

Date: October 24, 2006

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REPLACEMENT SHEET

~~"Prior Art"~~

Express Mail Label No.: EV961801322US

Date of Deposit: October 24, 2006

Application No. 10/723499

ANNOTATED SHEET 1/2

FIG. 4

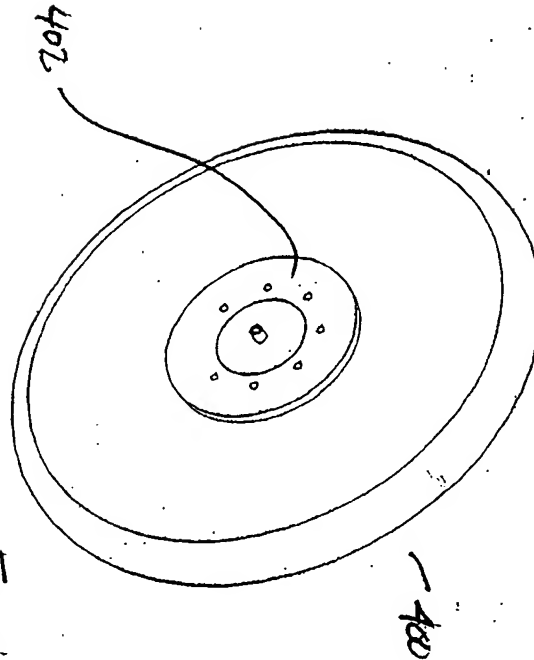


FIG. 4

REPLACEMENT SHEET

~~"Prior Art"~~

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ANNOTATED SHEET 2/2

FIG. 5

